

EXHIBIT 38

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

OREXO AB,

Plaintiff,

v.

MYLAN PHARMACEUTICALS INC.
and MYLAN INC.,

Defendants.

Honorable Freda L. Wolfson, U.S.D.J.
Honorable Lois H. Goodman, U.S.M.J.

Civil Action No. 3:11-cv-3788 (FLW)(LHG)

**DEFENDANTS/COUNTERCLAIM PLAINTIFFS MYLAN PHARMACEUTICALS
INC. AND MYLAN INC.'S PRELIMINARY PROPOSED CLAIM CONSTRUCTIONS**

Defendants/Counterclaim Plaintiffs Mylan Pharmaceuticals Inc. and Mylan Inc. (collectively, "Mylan"), by their undersigned attorneys, submit the following preliminary proposed claim constructions for the claim terms the parties contend should be construed by the Court under Local Patent Rule 4.2 and the revised schedule ordered by Magistrate Judge Lois H. Goodman on March 28, 2012.

Mylan has received little discovery from Plaintiff and no discovery from third parties. Mylan's investigation into extrinsic evidence also continues. Mylan reserves the right to supplement, amend, and modify its preliminary proposed constructions, and the evidence in support of those constructions, in light of any further discovery in this case and Mylan's investigation, to the extent permitted by the scheduling order or any subsequent order.

Moreover, claims are to be construed in light of the entire patent, prosecution history, and body of extrinsic evidence. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1313-14, 1321 (Fed. Cir. 2005). Indeed, the prosecution history and the patent must be read together as part of the complete intrinsic public record. *Id.* Mylan therefore generally identifies the entire '910

<u>TERM IN CLAIM</u>	<u>PROPOSED CONSTRUCTION</u>	<u>SUPPORT</u>
		<p>(Sept. 26, 2002 Office Action, p. 4 (ORM_00000159); <i>see also</i> May 19, 2003 Office Action, p. 2 (ORM_00000190).)</p> <p>“The most important aspect of the invention is the fact that the compound remains water-free so that the active agents do not dissolve too quickly.” (Sept. 26, 2002 Office Action, p. 5 (ORM_00000160); <i>see also</i> May 19, 2003 Office Action, p. 3 (ORM_00000191).)</p> <p>“[A]t the time the application was filed, one of ordinary skill in the art would have expected that an ordered mixture requires a relatively large volume of liquid in order to be effective. However, in the sublingual administration of an ordered mixture, the volume of liquid available as a solvent is limited to just a few millimeters.” (Feb. 26, 2003 Amendment, p. 6 (ORM_00000181).)</p> <p>Testimony from experts.</p>
<p>“ordered mixture of microparticles of at least one pharmaceutically active agent adhered to the surfaces of carrier particles”</p>	<p>The result of dry mixing microparticles of active agent with carrier particles so that the microparticles of at least one pharmaceutically active agent are finely dispersed and cover the surface of the carrier particles</p> <p>Microparticles have a weight-based mean particle size of no more than 24 microns.</p>	<p>“It is preferred to formulate the composition according to the invention by use of the technology for formulating rapidly dissolving ordered-mixture compositions disclosed in European patent EP 0 324 725. In these compositions, the drug in a finely dispersed state covers the surface of substantially larger carrier particles. Such compositions disintegrate rapidly in water, thereby dispersing their contents of microscopic drug particles.” (“910 patent, col. 3, lns. 26-34.)</p> <p>“It is known that ordered mixtures of a relatively coarse particulate, water-soluble, pharmaceutically acceptable carrier substance and smaller particles of at least one pharmaceutically active substance can be produced by means of a dry mixing process, in which the smaller particles adhere or bind to the surfaces of the larger carrier particles (C. Nyström et al., <i>J. Pharm. Pharmacol.</i> 38, pages 161-165, (1986); M. Westerberg et al, <i>International Journal of Pharmaceutics</i>, 28, pages 23-31, (1986). Because of their small particle size, the therapeutically</p>